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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/523,066	03/10/2000	Timothy P. Tully	1314.1058-0001	4462

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EXAMINER	
FORMAN, BETTY J	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 08/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/523,066	TULLY ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Petition of 1 February 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive in view of the Petition Decision of 3 August 2004.

The finality of that action is withdrawn.

Claim Rejections - 35 USC § 112

35 U.S.C. 112: First Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-10 and 16-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for identifying genes involved in transcription-dependent memory in drosophila, does not reasonably provide enablement for non-human animals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirements and whether undue experimentation would be required to make and use the claimed invention (see *In re Wands*, 858 F. 2d 731, 737, 8 USPQ 2d 1400, 1404, 1988). These factors include but are not limited to:

Breadth of the Claims

The claims are drawn to a method of identifying a gene or genes involved in transcription-dependent memory. The method includes steps of training non-human animals under conditions sufficient to induce transcription-dependent memory and removing RNA from brain tissue to analyze gene expression thereby identifying a gene related to the training.

The claims are written so broadly so as to encompass any non-human animal. The claimed non-human animals includes a very large and diverse genus of animals e.g. mammals, birds, reptiles, fish, worms, amoeba and etc. Furthermore, the claims are drawn to training all these non-human animals to induce transcription-dependent memory.

In contrast to the breadth of the claims, the specification teaches one species of the very large genus, that species being drosophila (Tables 1-4, Examples 1-9. The specification provides an example of one additional species i.e. rat, wherein expression of a single protein is analyzed (Examples 10-17). However, the specification does not teach the broadly claimed genus of non-human animals or training protocols sufficient to induce transcription-dependent memory in various species of the genus.

While the specification is enabling for training and gene identification in drosophila, the specification is not enabling for the broadly claimed invention.

Nature of the Invention

The claims are drawn to a method of identifying a gene or genes involved in transcription-dependent memory. The method includes steps of training non-human animals under conditions sufficient to induce transcription-dependent memory and removing RNA from brain tissue to analyze gene expression thereby identifying a gene related to the training.

The nature of the invention is such that training animals to induce transcription memory is species-specific as evidenced by the specification wherein it is taught that "specific

training protocols are expected to yield CMGs in animals" (page 20, lines 7-8). The specification provides examples of the very specific training protocols for drosophila including time, duration and spacing of training steps (page 10, lines 2-21). The specification further teaches differing training protocols for rats requiring specially designed cages and startle chambers (page 19, line 21-page 20, line 8 and Examples 9-10). The differences between the training of drosophila and rats illustrates the nature of the invention is such that species-specific conditions are required to induce transcription-dependent memory

However, the specification does not teach the "specific training protocols" (page 20, line 9) for the claimed genus of non-human animals that would enable one of skill in the art to make and use the invention as claimed.

State of the Prior Art

The claims are drawn to a method of identifying a gene or genes involved in transcription-dependent memory. The state of the prior art is such that CREB expression has a role in drosophila memory (Yin et al Cell, 1994, 79: 49-58) wherein drosophila-specific training protocols are described (page 55). Yin et al further suggest that CREB expression in other animals is involved in memory (page 54). However, the prior art and the specification do not teach or describe training protocols and/or conditions sufficient to induce transcription-dependent memory in non-human animals as instantly claimed. Therefore, neither the specification nor the prior art of record provide a teaching that would enable one of skill in the art to make and use the invention as claimed.

Level of Predictability in the Art

The claims are drawn to a method of identifying a gene or genes involved in transcription-dependent memory. The method includes steps of training non-human animals

under conditions sufficient to induce transcription-dependent memory and removing RNA from brain tissue to analyze gene expression thereby identifying a gene related to the training. The specification teaches conditions to induce transcription-dependent memory in drosophila and rats wherein the conditions differ and are specific for the animal (drosophila, page 10, lines 2-21 and rat, page 19, line 21-page 20, line 8 and Examples 9-10). The specification further teaches "specific training protocols are expected to yield CMG in animals" (page 20, line 9). However, the specification does not teach those "specific" protocols. Because the protocol for training drosophila differs so greatly from the protocol for training rats, the ability to predict specific protocols for training the very large and divers genus of non-human animals would be very low. Therefore, the level of predictability in the art is very low with regard to training conditions sufficient to induce transcription-dependent memory in non-human animals.

Existence of Working Examples

The claims are drawn to a method of identifying a gene or genes involved in transcription-dependent memory. The specification provides examples of the very specific training protocols inducing transcription-dependent memory in drosophila including time, duration and spacing of training steps (page 10, lines 2-21). The specification further teaches differing training protocols for rats requiring specially designed cages and startle chambers (page 19, line 21-page 20, line 8 and Examples 9-10). However, the specification does not provide working examples of the broadly claimed genus of non-human animals that would enable one of ordinary skill in the art to make and use the invention as claimed.

Quantity of Experimentation Required

In view of the breadth of the claims being drawn to a very large and diverse genus of animals and their training to induce transcription-dependent memory; in view of the nature of the invention such that training animals to induce transcription memory is species-specific as

evidenced by the specification wherein it is taught that "specific training protocols are expected to yield CMGs in animals" (page 20, lines 7-8); in view of the state of the prior art which does not teach or describe training protocols and/or conditions sufficient to induce transcription-dependent memory in non-human animals as instantly claimed; in view of the of unpredictability in the art with regard to training protocols as evidenced by the differing protocols for drosophila and rats; and in view of the lack of working examples of the broadly claimed invention, it would require undue experimentation for one skilled in the art to make and use the invention as claimed.

35 USC § 112: Second Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-10 are indefinite in Claim 1, (b) and (c) for the recitation RNA, but it is unclear whether total RNA is extracted. DNA is synthesized from the RNA in step (c) which suggests the RNA is mRNA and the DNA is cDNA. It is suggested the claims be amended to clarify.

Claims 1-10 are indefinite in Claim 1, step (f) for the recitation "the signal detected in a control" because the recitation lacks proper antecedent basis in the claim. It is suggested the claim be amended to replace "the" with "a".

Claims 11-15 are indefinite in Claim 11, (b) and (c) for the recitation RNA, but it is unclear whether total RNA is extracted. cDNA is synthesized from the RNA in step (c) which suggests the RNA is mRNA. It is suggested the claims be amended to clarify.

Claims 11-15 are further indefinite in Claim 11, step (d), for the recitation "DNA probes" because the recitation lacks proper antecedent basis in the "cDNA probes" of step (c).

Claims 11-15 are indefinite in Claim 11, step (f) for the recitation "the signal detected in a control" because the recitation lacks proper antecedent basis in the claim. It is suggested the claim be amended to replace "the" with "a".

Claims 16-23 are indefinite in Claim 16, (b) and (c) for the recitation RNA, but it is unclear whether total RNA is extracted. DNA is synthesized from the RNA in step (c) which suggests the RNA is mRNA and the DNA is cDNA. It is suggested the claims be amended to clarify.

Claims 16-23 are indefinite in Claim 16, step (f) for the recitation "the signal detected in a control" because the recitation lacks proper antecedent basis in the claim. It is suggested the claim be amended to replace "the" with "a".

Claims 24-26 are indefinite in Claim 24, (b) and (c) for the recitation RNA, but it is unclear whether total RNA is extracted. cDNA is synthesized from the RNA in step (c) which suggests the RNA is mRNA. It is suggested the claims be amended to clarify.

Claims 24-26 are further indefinite in Claim 24, step (d), for the recitation "DNA probes" because the recitation lacks proper antecedent basis in the "cDNA probes" of step (c).

Claims 24-26 are indefinite in Claim 24, step (f) for the recitation "the signal detected in a control" because the recitation lacks proper antecedent basis in the claim. It is suggested the claim be amended to replace "the" with "a".

Conclusion

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
August 18, 2004